Remarks/Arguments

This Response is being filed in conjunction with a Request for Continuing Examination under the provisions of 37 CFR § 1.114 and the appropriate fee. No new matter has been added. It is respectfully submitted that this Response addresses all of the issues raised by the Examiner in the above-identified Office Action and that the subject application now is in condition for allowance. Accordingly, reconsideration of the subject application is requested in view of the foregoing amendments and following remarks.

Claims 1-21 and 23 have been cancelled. Claims 22 and 24-27 are currently pending. Claims 22 and 24-27 stand rejected under 35 U.S.C. §103(a) and claims 22 and 24-27 stand rejected under 35 U.S.C. §112, second paragraph. Applicants have amended claim 22 to address the Examiner's rejections.

CLAIM REJECTIONS UNDER 35 U.S.C. §112

Claims 22 and 24-27 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. In particular, claim 22 introduced the step of "identifying the association between a fibrinogen degradation product (FDP) and common oncogenic proteolytic processes" in concert with the steps of contacting and determining the presence or absence of said FDP.

Additionally a typographical error in claim 22 was corrected changing that last line of the claim to read "fibrinogen fragments D and E are not detected." Fragment E was incorrectly cited as "B" in the last claim listing. The Examiner is directed to the Response to Office Action mailed December 19, 2001 where claim 22 was first introduced. In the subsequent response, dated January 9, 2004, the fragment was mistakenly identified as "B."

Applicants have deleted the phrase "identifying the association between a fibrinogen degradation product (FDP) and common oncogenic proteolytic processes" from amended claim 22, thereby rendering the rejection moot. The Examiner is hereby requested to withdraw this rejection.

CLAIM REJECTIONS UNDER 35 U.S.C. §103(a)

Claims 22 and 24-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Wojtukiewicz et al. (Polish Jnl. Pharm., 1996, Col. 48, pages 229-232) and as further evidenced by US Patent No. 4,851,334 (Kudryk et al., 25 July 1989). This rejection was maintained from the previous Office Action dated July 11, 2003.

The Examiner stated in the Office Action dated July 11, 2003 that Wojtukiewicz et al. teach a method for detecting cancer (gastric cancer) in human subjects comprising contacting a biological sample obtained from a subject with a monoclonal antibody T2G1 (page 230). The Examiner further stated that this monoclonal antibody is disclosed in US Patent No. 4,851,334 and that this monoclonal antibody is monospecific for a single determinant on the peptide fragment of the beta chain of human fibrin II containing amino acid residues 15-42 (column 5, line 63+).

According to MPEP 2143, in order to establish a case of *prima facie* obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations.

Applicants respectfully assert that Wojtukiewicz et al. does not teach a method of detecting cancer. Wojtukiewicz et al. disclose experiments investigating the presence of fibrin degradation products in gastric cancer tissue for the purpose of studying "whether there is local thrombin generation and subsequent fibrin formation in gastric carcinoma tissue" (p 230). Wojtukiewicz et al. were interested in thrombosis and DIC in patients with gastric cancer and the causes of those conditions. Nowhere in this reference do the authors suggest that antibodies to fibrin can be used to diagnose cancer by detecting the presence of fibrin degradation products in biological samples. Additionally Wojtukiewicz et al. detects the fibrin degradation products in cancer tissue itself, not in a biological sample as defined in the claims of the present application. The present invention is directed to detecting the fibrin degradation product in a biological

sample selected from the group consisting of blood, serum, plasma, urine, cervical secretions, bronchial aspirates, sputum, saliva, feces, synovial fluid and cerebrospinal fluid. Wojtukiewicz et al. do not teach or suggest the present invention.

US Patent No. 4,851,334 to Kudryk discloses a monoclonal antibody to the fibrin beta chain amino acid residues 15-42 that may or may not be of equivalent specificity to the monoclonal antibody of the present invention. However, the present application does not claim a monoclonal antibody of this specificity. The present application claims a method of detecting cancer using a monoclonal antibody of the disclosed specificity. US Patent No. 4,851,334 does not teach or suggest that the T2G1 monoclonal antibody could be used to detect cancer.

Therefore, since there is no suggestion or motivation in either of the two references to modify or combine the references, they do not teach or suggest all the claim limitations and there is no reasonable expectation of success in developing a method of detecting cancer using the teachings of these two references, Applicants assert that a *prima facie* case of obviousness has not been made. Therefore Applicants respectfully request that the 35 U.S.C. §103(a) rejection of claims 22 and 24-27 be withdrawn.

CLAIM REJECTIONS UNDER 35 U.S.C. §102(b)

In a previous Office Action of July 11, 2003, the Examiner also rejected claims 22 and 24-27 under 35 U.S.C. §102(b) as being anticipated by Wojtukiewicz et al. (Polish Jnl. Pharm., 1996, Col. 48, pages 229-232) and as further evidenced by US Patent No. 4,851,334 (Kudryk et al., 25 July 1989).

Wojtukiewicz et al. does not disclose a method of detecting cancer and therefore Wojtukiewicz et al. does not possess all of the elements found in claim 22 and cannot, by definition, anticipate claim 22. Consequently, Applicants respectfully request that the Examiner withdraw this basis for rejection and allow the pending claims.

Concluding Remarks

The Applicants have amended the pending claims of the subject application to address the Examiner' s rejections and to place the remaining claims in condition for allowance. Further, the Applicants have presented arguments demonstrating the patentable novelty and non-obviousness of the amended claims over the cited references. Therefore, the Applicants respectfully assert that the claims contain allowable subject matter and request that the rejections and objections be withdrawn and that the Examiner allow the presently pending claims.

If the Examiner believes that a telephonic interview with the Applicants or the Applicants' attorney will advance the allowance of this case, the Examiner is requested to contact the undersigned at the telephone number provided below.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

Dated: 12/27/04

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